UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,713	07/08/1999	HERWIG BUCHHOLZ	MERCK-1900	7039

23599 7590 05/19/2004

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/349,713	BUCHHOLZ ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/2003, 1/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-14 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-14 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 27, 2004 has been entered.

Amendment filed on June 1, 2003 has been entered. Claims 1-10, 12-14, 26 are pending. Any rejection that is not addressed here is considered obviated in view of the amendments.

Claim Objections

Claims 1 and all dependent claims thereof are objected to because of the following minor informalities: the limitation of "a glycoside of any of the above other components," is confusing. It is not clear to which other components is applicant referring. Appropriate correction is required to clarify this language.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12-14, 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-24 of U.S. Patent No. 6,491,948. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of pending claims are anticipated with those already patented.

Claim 1 encompass pharmaceutical compositions comprising isoquercitrin and ascorbic acid. The patented claims are directed to oral formulations of isoquercitrin and ascorbic acid. Accordingly, one of ordinary skill in the art in possession of the patented claims would have practiced the instant pending claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-8, 12, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abou-Karam et al (J Nat Prod. 1992, Oct; 55(10):1525-7) in view of Hovi et al (Antiviral Research 27 (1995) 263-270) and Bean US Patent 4,132,782.

Abou-Karam teaches that isoquercitrin has profound activity against simplex virus. Abou-Karam also teaches suitable antiviral doses of isoquercitrin (see abstract, and page 1526). Abou-Karam doesn't teach the use of isoquercitrin with ascorbic acid.

Hovi teaches that ascorbic acid has substantial antiviral effects against herpes simplex virus (abstract, pages 268-270).

Bean is further used to show that isoquercitrin containing topical compositions with carotene and other vitamins are known in the art to be useful for suppressing herpes simplex virus.

It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Claims

that require no more than mixing together of two conventional compounds used for the same purpose would be *prima facia* obvious.

In the instant case, it would have been obvious to one of ordinary skill in the art at the time of invention to combine isoquercitrin of Aou-Karam at suitable anti herpes virus activity with ascorbic acid of Hovi, because mixing these two elements to create a third composition for treatment of herpes simplex virus would have been well within purview of an ordinary artisan and further as taught by Bean, the ordinary skill in the art would have had a reasonable expectation of success in using a topical formulation containing isoquercitrin for treatment of herpes simplex virus.

Claims 1-10, 12-14, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abou-Karam et al (J Nat Prod. 1992, Oct;55(10):1525-7) in view of Hovi et al (Antiviral Research 27 (1995) 263-270) and Bean US Patent 4,132,782 as applied to claims 1-4, 6-8, 12, 26 above, and further in view of Lanzendorfer et al WO 96/18381.

The combined teachings of Abou-Karam, Hovi and Bean are described above. The combined teachings of the cited references do not explicitly teach oral formulation of isoquercitrin or topical formulations comprising a UV filtering agent.

Lanzendorfer is used to show that conventional nature of art in combining flavones in oral and topical compositions. Lanzendorfer discloses topical and oral flavonoid containing compositions comprising various vitamins, UVB or UVA filters and at least one flavone including isoquecertin derivatives. Given the fact that isoquecertin is one of the four subspecies of quecertin, the teachings of Lanzendorfer also encompass

utility of isoquecertin. Lanzendorfer also indicates antiviral activity with his composition (see abstract, page 3-5, 43, 54-60, claims 1-7, and examples, example 27 is an oral preparation). Lanzendorfer does not specifically teach combining isoquercitrin with ascorbic acid, carotene or other vitamins as an antiviral formuation.

Nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of Lanzendorfer and modify the combination of isoquercitrin and ascorbic acid of Abou-Karma and Hovi for the purposes of preparing a topical composition of isoquercitrin with a UV filter, because as taught by Lanzendorfer preparing such topical formulations of flavones well within purview of one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated to formulate topical formulations to reduce systemic side effects of antivirus drugs.

Further, it would have been obvious to one of ordinary skill in the art at the time of invention to prepare such compositions in oral form because formulating such compositions with a new carrier system is a matter of design choice and well within the level of an ordinary artisan.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ss

RUSSELL TRAVERS
PRIMARY EXAMINER